## REMARKS

### 1. The Amendments and the Support Therefor

Three claims (21, 24, and 26) have been canceled, three new claims (27-29) have been added, and claims 1, 15, 23, and 25 have been amended to leave claims 1-8 and 15-26 in the application. No fees should be due for the new claims because they add no claims beyond those already paid for. No new matter has been added by the amendments or new claims, which find support as follows:

- Claim 1: Amended to incorporate claim 21, now canceled.
- Claim 15: Amended to incorporate the matter of claims 21 / 24 / 26.
- Claim 23: Amended to incorporate claim 24, now canceled.
- Claim 25: Amended to incorporate claim 26, now canceled (and also amended to better address antecedent basis).
- New claims 27-29: Find support at page 6, next-to-last paragraph to page 7, first paragraph; page 13, second paragraph onward.

Further comments regarding the new claims are set out below at Section 3.

### 2. Rejection of Claims 1-8 and 15-26 under 35 USC §103 in view of U.S. Patent 6,582,581 to *Bowe* and U.S. Patent 4,721,118 to *Harris*

Kindly reconsider and withdraw these rejections since the invention, when considered as a whole (as required by §103), would not in fact have been obvious at the time the invention was made to a person having ordinary skill in the art. This is particularly true in view of the amendments to the claims to clearly limit them to ablation catheters – which, as noted in the Background section of the present application, are the focus of the application – rather than stimulation/measurement catheters (e.g., pacing catheters). Before discussing unobviousness in detail, it is initially useful to review the cited references.

**U.S. Patent 6,582,581 to *Bowe*** involves a device for use in cardiac tissue ablation having a catheter 30 with leads 15 leading to spaced conductive band (ring) electrodes 32 (FIG. 1, column 7 lines 16-26), with the conductors preferably being made of metal (column 7 lines 40-43). Temperature sensors 40 are situated next to each of the ring / band electrodes 32 (column 7 line 65-

column 8 line 5). Turning to FIGS. 2-3, the catheter has an internal stylet 104 formed into a bent shape (with the stylet serving as a "spine" which defines the catheter's shape), and also has an outer sheath 118 covering the stylet 104 and upon which the electrodes 32 are provided (column 8 lines 16-26, column 9 line 61-column 10 line 2). The sheath 118 also has an internal deflectable steering tendon 102 alongside the stylet 104, wherein the tendon 102 may be pulled to straighten the catheter (column 8 lines 26-32, column 10 lines 24-34, 46-61). An outer sleeve 100 fit about the sheath 118 can be advanced over the bent sheath 118 to straighten it, or can be retracted to allow the stylet 104 to bend the sheath 118 (column 8 lines 43-52). Thus, by moving the steering tendon 102 within the sheath 118 or moving the sleeve 100 over the sheath 118, the bending force of the stylet 104 may be defeated or enabled to allow the electrodes 32 to move into contact with cardiac tissue as desired for ablation of the tissue (column 11 line 27 onward).

**U.S. Patent 4,721,118 to *Harris*** involves a device for use in cardiac pacing (column 1 lines 16-20, column 3 lines 6-8, etc.) having a carbon fiber lead (column 3 lines 29-41) terminating in a metallic electrode, or alternatively in a terminal electrode simply formed of a bare end of the carbon fiber bundles (column 4 lines 53-55). The lead is noted as being described in greater depth in U.S. Patent 4,198,991 to *Harris* (column 3 lines 36-41, column 4 lines 12-17, etc.), which in turn describes how the carbon fiber lead – which is wound in a helix within the device (FIG. 3 at 25, column 3 lines 53-60) – is used because it provides greater fatigue / damage resistance than a helical metal (Elgiloy) lead ('991 at column 5 lines 30-40), while having substantially the same conductivity as Elgiloy ('991 at column 5 lines 29-31).[1] (This similar conductivity is attained because a helical Elgiloy wire has relatively long linear length, and thus relatively high resistance, whereas stiffer carbon fibers can be shorter, and can thus have overall resistance similar to that of Elgiloy despite the fact that "carbon filaments are relatively poor conductors as compared with metal and therefore do not suggest themselves as wire substitutes." See '991 at column 3 line 53-column 4 line 14.) Where a metal conductor (e.g., the electrode) is joined to the carbon fibers, this is done via conductive epoxy adhesive ('991 at column 3 lines 31-41, column 4 lines 27-31).

[1] The *Harris* lead is noted as being an improvement on a prior lead using Elgiloy. See *Harris* '991 at column 1 line 39 onward.

As discussed in the present application, there are important structural and functional differences between electrical pacing and/or measurement devices (i.e., devices used to measure electrical properties of the heart, and/or to deliver electrical stimulation to the heart, such as *Harris*), and electrical ablation devices (devices used to electrically destroy a portion of the heart tissue, such as *Bowe*). Most notably, cardiac ablation requires *significantly* higher energy delivery than cardiac stimulation: the ablation energy must cauterize or otherwise destroy tissue, rather than simply stimulating it (see, e.g., the paragraph bridging pages 3-4 of the present application). This is amplified by the fact that whereas stimulation catheters are usually unipolar or bipolar (i.e., they tend to have only one or two electrodes), ablation catheters generally have multiple electrodes, any one or more of which is to serve an ablation function (see, e.g., column 7 lines 31-37 of *Bowe*).

As also discussed in the present application, electrode catheters which use carbon fiber conductors *for cardiac stimulation* are known from several prior references, including *Harris* (see second paragraph of page 3). *Harris* notes that carbon fibers are used because they can provide greater fatigue resistance than a *metal (Elgiloy) lead*, despite the well-known fact that "carbon filaments are relatively poor conductors as compared with metal and therefore do not suggest themselves as wire substitutes." However, it is notable that *Harris* is over two decades old, and advances in material science since *Harris*' time have led to a large variety of fatigue-resistant conductive metals that can be used in lieu of Elgiloy. Thus, (non-helical) *wire* leads are conventionally used in the art, as illustrated by *Bowe*, which uses (non-helical) wire leads (15 in FIG. 1, or 128 in FIGS. 10-12). Metallic wire leads, being far better conductors than carbon fiber (particularly if not made of long lengths formed into coils), are far better able to carry the energy needed for ablation, particularly where ablation energy is to be delivered via multiple electrodes. Wire leads also tend to be more flexible than carbon fibers, which are quite stiff. Since ablation catheters generally need to be highly maneuverable (as illustrated by *Bowe*'s discussion of catheter positioning, see FIGS. 14-16 and column 10 line 62 onward), the flexibility of wire is very useful in ablation catheters.

The end result is that an ordinary artisan who knew the state of the art, including *Bowe* and *Harris*, would not in fact contemplate the use of carbon conductors in an ablation catheter (such as

that of *Bowe*, and/or the one claimed), as opposed to a stimulation catheter (such as that of *Harris*): the poor conductivity of carbon conductors makes it exceedingly difficult to deliver the energy needed for ablation, and moreover their stiffness makes them impractical for use in an ablation catheter, which is preferably highly maneuverable. As noted by *Harris*, "carbon filaments are relatively poor conductors as compared with metal and therefore do not suggest themselves as wire substitutes" – and this statement was made when the *Harris* application was filed in 1978, over thirty years ago. Because advances in materials science have since then yielded numerous alloys / wires with properties superior to the Elgiloy conductors that *Harris* sought to replace, *Harris*' statements regarding the use of metal wire over carbon are doubly true today: no ordinary artisan would in fact consider the use of carbon conductors in an ablation catheter in lieu of wire. Carbon conductors simply offer too many disadvantages for ablation catheters, with no offsetting advantages. As explained in MPEP 2142, for a claimed invention to be obvious, it must be such that it would be contemplated by an ordinary artisan who had no actual knowledge of the claimed invention:

> To reach a proper determination under 35 U.S.C. 103, the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.[2]

We submit that if this process is followed, with the claimed invention being placed out of mind and the state of the art at the time of invention being objectively considered from the standpoint of an

[2] In this respect, the Court of Appeals for the Federal Circuit and the Supreme Court have emphasized the fact-intensive nature of the obviousness analysis, and how the analysis hinges on the specific circumstances of each case. As noted by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007), "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." Thus, when the facts of this field of art are fully taken into account, it cannot simply be declared that an ordinary artisan would adopt carbon conductors in *Bowe* because "a predictable result would ensue": the predicted result is poor, and thus no artisan would follow this route.

ordinary artisan, it cannot fairly be said that the ordinary artisan would contemplate or consider the claimed invention: there is simply no apparent reason to use carbon conductors in an ablation catheter.

Regarding ***claim 17***, while the Office Action states that "[t]he diameter of the second conductor is also deemed to have been an obvious design expedient to optimize performance of the device since different diameter conductors are well known in the art," there does not in fact seem to be any art of record in the field of ablation catheters using different diameter conductors, and there's no apparent reason to adopt the claimed arrangement.[3] This is particularly true because carbon conductors of different diameters will have different stiffnesses, and the use of such conductors would seem to impart difficult and/or odd bendability to an ablation catheter (which, as previously noted, desirably has high bendability).

Regarding ***claim 18***, it is notable that if carbon conductors were used in an ablation catheter, their high resistance would seem to make them susceptible to heating, which would in turn tend to skew the results of any temperature sensors. Thus, when the claimed invention is considered *as a whole* (in accordance with §103), the holding of obviousness should be reconsidered.

***Claim 19*** is submitted to be allowable for fundamentally the same reasons as claims 27-29, discussed below.

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[3] Also, regarding the conclusion of "obvious design expedient," note that the USPTO has recognized that a conclusory statement of this nature is an insufficient rationale for a proper obviousness rejection; see, e.g., the USPTO's guidelines for §103 rejections of business methods at

http://www.uspto.gov/web/menu/busmethp/busmeth103rej.htm

which states that:

> [a] simple statement that a difference is a 'design choice' or 'lacks an advantage or unexpected result' is insufficient rationale to support a well written and legally sufficient rejection. These are conclusions, not statements of fact.

While this citation is taken from the guidelines for business methods – inventions which are not the same as the one in question here – its rationale is no less applicable here, particularly since the Introduction for the guidelines states that the bases for rejections of business methods are the same as "for inventions in any field of technology."

## 3. New Claims 27-29

***Claims 27-29*** are also submitted to be unobvious because here too, an ordinary artisan would not in fact consider or contemplate the claimed arrangement: there is no apparent reason whatsoever to construct the claimed arrangement, and furthermore the claimed arrangement would seem to generate difficulties owing to the difficulties in making good electrical connection between carbon and other media (e.g., the tendency for high impedance / resistance junctures between carbon and metal, carbon not being readily connected to the metal via solder or the like).

## 4. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

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